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Commissioner for Patents  
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By:   
Aaron Hokamura

**PATENT**  
Attorney Docket No.: 082368-001500US  
Client Reference No.: E1-A0305Y1P-US

**Rec'd PCT/PTO 04 OCT 2005**

**10/518472**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

ITO and SAITO

Application No.: 10/518,472

Filing Date: to be assigned

Int'l Application No.: PCT/JP03/07721

Int'l Filing Date: June 18, 2003

For: PRIMARY CULTURED  
ADIPOCYTES FOR GENE THERAPY

Examiner: Not yet assigned

Art Unit: Not yet assigned

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of references AB through CL and CN through DK are enclosed. Reference AA (U.S. Patent No. 4,829,000) is not enclosed in accordance with the USPTO waiver of the requirement under 37 CFR 1.98 (a)(2)(i) pursuant to 1287 OG 163.

A copy of reference CM (Raper and Wilson, Cell Transplant. 2(5):381-400, 1993) is not enclosed since it was cited in the International Search Report in the corresponding PCT application, and, as such, should have been provided directly by the WIPO under the exchange program between the USPTO, the EPO and the JPO.

Also cited in the International Search Report are references AY (Christensen, 2001), BN (Hertzel, 2000) and CG (Nagamatsu, 2001). A copy of the Search Report is enclosed.

References AL, CW, CY and DB are not in English. English language translation of these references are provided.


Reference AM is also not in the English language. However, Reference AM is an equivalent application to the English language reference AF (WO 97/49827) and the disclosures are cumulative. Therefore, pursuant to 37 C.F.R. 1.98(c) and MPEP 609(III)(A)(3), an English translation is not required, nor provided.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
Kevin Bastian  
Reg. No. 34,774

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60601553 v1

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/518,472	
			Filing Date		
			First Named Inventor	Ito, Masashi	
			Art Unit	Not yet assigned	
			Examiner Name	Not yet assigned	
Sheet	1	of	6	Attorney Docket Number	082368-001500US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	4,829,000	05-09-1989	Kleinman et al.	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AB	WO	86/07595	A1	12-31-1986	The Salk Institute for Biological Studies		<input type="checkbox"/>
	AC	WO	87/01728	A1	03-26-1987	Biotechnology Research Partners, Ltd.		<input type="checkbox"/>
	AD	WO	87/03885	A1	07-02-1987	Synergen, Inc.		<input type="checkbox"/>
	AE	WO	89/04832	A1	06-01-1989	Amgen Inc.		<input type="checkbox"/>
	AF	WO	97/49827	A2/A3	12-31-1997	Cornell Research Foundation, Inc.		<input type="checkbox"/>
	AG	EP	0 237 966	A2/A3	09-23-1987	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	AH	EP	0 281 822	A2/A3	09-14-1988	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	AI	EP	0 326 907	A1	08-09-1989	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	AJ	EP	0 394 951	A1	10-31-1990	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	AK	EP	0 493 737	A1	07-08-1992	Kaken Pharmaceutical Co., Ltd.		<input type="checkbox"/>
	AL	JP	11-127870		05-18-1999	Mayo Foundation for Medical Education and Research		<input checked="" type="checkbox"/>
	AM	JP	2000-514421		10-31-2000	Cornell Research Foundation, Inc.		<input type="checkbox"/>

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60601553 v1

Substitute for form 1449B/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10/518,472	
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NON PATENT LITERATURE DOCUMENTS			
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	AN	ABRAHAM, Judith A. <i>et al.</i> , "Human basic fibroblast growth factor: nucleotide sequence and genomic organization," <u>The EMBO Journal</u> 5(10):2523-2528 (1986)	
	AO	ABUMRAD, Nada A. <i>et al.</i> , "Cloning of a rat adipocyte membrane protein implicated in binding or transport of long-chain fatty acids that is induced during preadipocyte differentiation," <u>The Journal of Biological Chemistry</u> 268(24):17665-17668 (August 25, 1993)	
	AP	ARAI, Tohru <i>et al.</i> , "A new system for stringent, high-titer vesicular stomatitis virus G protein-pseudotyped retrovirus vector induction by introduction of Cre recombinase into stable prepackaging cell lines," <u>Journal of Virology</u> 72(2):1115-1121 (February 1998)	
	AQ	BRADLEY, Richard L. <i>et al.</i> , "The adipocyte as a secretory organ: Mechanisms of vesicle transport and secretory pathways," <u>Recent Prog. Horm. Res.</u> 56:329-358 (2001)	
	AR	BURNS, Jane C. <i>et al.</i> , "Vesicular stomatitis virus G glycoprotein pseudotyped retroviral vectors: Concentration to very high titer and efficient gene transfer into mammalian and nonmammalian cells," <u>Proc. Natl. Acad. Sci. U.S.A.</u> 90:8033-8037 (September 1993)	
	AS	BYUN, J. <i>et al.</i> , "A simple and rapid method for the determination of recombinant retrovirus titer by G418 selection," <u>Gene Therapy</u> 3:1018-1020 (1996)	
	AT	CASHION, L.M. <i>et al.</i> , "Use of enhanced green fluorescent protein to optimize and quantitate infection of target cells with recombinant retroviruses," <u>BioTechniques</u> 26(5):924-930 (May 1999)	
	AU	CHALLITA, Pia-Maria and Donald B. Kohn, "Lack of expression from a retroviral vector after transduction of murine hematopoietic stem cells is associated with methylation <i>in vivo</i> ," <u>Proc. Natl. Acad. Sci. U.S.A.</u> 91:2567-2571 (March 1994)	
	AV	CHEN, Hui <i>et al.</i> , "Protein-tyrosine phosphatases PTP1B and Syp are modulators of insulin-stimulated translocation of GLUT4 in transfected rat adipose cells," <u>The Journal of Biological Chemistry</u> 272(12):8026-8031 (March 21, 1997)	
	AW	CHEN, Wen Yong <i>et al.</i> , "Reactivation of silenced, virally transduced genes by inhibitors of histone deacetylase," <u>Proc. Natl. Acad. Sci. U.S.A.</u> 94:5798-5803 (May 1997)	
	AX	CHEN, Wen Yong and Tim M. Townes, "Molecular mechanism for silencing virally transduced genes involves histone deacetylation and chromatin condensation," <u>PNAS</u> 97(1):377-382 (January 4, 2000)	
	AY	CHRISTENSEN, Rikke <i>et al.</i> , "Cutaneous gene therapy -- an update," <u>Histochem. Cell Biol.</u> 115(1):73-82 (January 2001)	
	AZ	CLAUDIO, Pier Paolo <i>et al.</i> , "Application of the primer <i>in situ</i> DNA synthesis (PRINS) technique to titer recombinant virus and evaluation of the efficiency of viral transduction," <u>Analytical Biochemistry</u> 291:96-101 (2001)	
	BA	DILLON, Joseph S. <i>et al.</i> , "Cloning and functional expression of the human glucagon-like peptide-1 (GLP-1) receptor," <u>Endocrinology</u> 133(4):1907-1910 (1993)	
	BB	DRUCKER, Daniel J., "Glucagon-like peptides," <u>Diabetes</u> 47:159-169 (February 1998)	
	BC	DRUCKER, Daniel J., "Development of glucagons-like peptide-1-based pharmaceuticals as therapeutic agents for the treatment of diabetes," <u>Current Pharmaceutical Design</u> 7:1399-1412 (2001)	
	BD	DRUCKER, Daniel J., "Minireview: the glucagon-like peptides," <u>Endocrinology</u> 142(2):521-527 (2001)	

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			Application Number	10/518,472	
			Filing Date		
			First Named Inventor	Ito, Masashi	
			Art Unit	Not yet assigned	
			Examiner Name	Not yet assigned	
Sheet	3	of	6	Attorney Docket Number	082368-001500US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BE	DRUCKER, Daniel J., "Biological actions and therapeutic potential of the glucagons-like peptides," <u>Gastroenterology</u> 122:531-544 (2002)	
	BF	DRUCKER, Daniel J. <i>et al.</i> , "Glucagon-like peptide I stimulates insulin gene expression and increases cyclic AMP levels in a rat islet cell line," <u>Proc. Natl. Acad. Sci. U.S.A.</u> 84:3434-3438 (May 1987)	
	BG	EMI, Nobuhiko <i>et al.</i> , "Pseudotype formation of murine leukemia virus with the G protein of vesicular stomatitis virus," <u>Journal of Virology</u> 65(3):1202-1207 (March 1991)	
	BH	GenBank Accession No. K02729, "Mouse leukemia virus (amphotropic)", August 1, 2002 <a href="http://www.ncbi.nlm.nih.gov/entrez">http://www.ncbi.nlm.nih.gov/entrez</a>	
	BI	GenBank Accession No. NP_002053, "glucagon-like peptide 1 receptor [Homo sapiens]", April 23, 2005 <a href="http://www.ncbi.nlm.nih.gov/entrez">http://www.ncbi.nlm.nih.gov/entrez</a>	
	BJ	GOTO, Masaki <i>et al.</i> , "Inhibitory effect of E3330, a novel quinine derivative able to suppress tumor necrosis factor- $\alpha$ generation, on activation of nuclear factor- $\kappa$ B," <u>Molecular Pharmacology</u> 49:860-873 (1996)	
	BK	GRAZIANO, Michael P. <i>et al.</i> , "Cloning and functional expression of a human glucagon-like peptide-1 receptor," <u>Biochemical and Biophysical Research Communications</u> 196(1):141-146 (October 15, 1993)	
	BL	GROSKREUTZ, Debyra J. <i>et al.</i> , "Genetically engineered proinsulin constitutively processed and secreted as mature, active insulin," <u>The Journal of Biological Chemistry</u> 269(8):6241-6245 (February 25, 1994)	
	BM	HAUNER, Hans <i>et al.</i> , "Promoting effect of glucocorticoids on the differentiation of human adipocyte precursor cells cultured in a chemically defined medium," <u>J. Clin. Invest.</u> 84:1663-1670 (November 1989)	
	BN	HERTZEL, Ann Vogel <i>et al.</i> , "Adenovirus-mediated gene transfer in primary murine adipocytes," <u>Journal of Lipid Research</u> 41:1082-1086 (2000)	
	BO	HOEBEN, Rob C. <i>et al.</i> , "Inactivation of the Moloney murine leukemia virus long terminal repeat in murine fibroblast cell lines is associated with methylation and dependent on its chromosomal position," <u>Journal of Virology</u> 65(2):904-912 (February 1991)	
	BP	JAHNER, Detlev and Rudolf Jaenisch, "Retrovirus-induced <i>de novo</i> methylation of flanking host sequences correlates with gene inactivity," <u>Nature</u> 315:594-597 (June 13, 1985)	
	BQ	JOHNSTON, James and Christopher Power, "Productive infection of human peripheral blood mononuclear cells by feline immunodeficiency virus: implications for vector development," <u>Journal of Virology</u> 73(3):2491-2498 (March 1999)	
	BR	JOHNSTON, Julie C. <i>et al.</i> , "Minimum requirements for efficient transduction of dividing and nondividing cells by feline immunodeficiency virus vectors," <u>Journal of Virology</u> 73(6):4991-5000 (June 1999)	
	BS	KAPLITT, Michael G. <i>et al.</i> , "Long-term gene expression and phenotypic correction using adeno-associated virus vectors in the mammalian brain," <u>Nature Genetics</u> 8:148-154 (October 1994)	
	BT	KAY, Mark A. <i>et al.</i> , "Viral vectors for gene therapy: the art of turning infectious agents into vehicles of therapeutics," <u>Nature Medicine</u> 7(1):33-40 (January 2001)	
	BU	KESSLER, Paul D. <i>et al.</i> , "Gene delivery to skeletal muscle results in sustained expression and systemic delivery of a therapeutic protein," <u>Proc. Natl. Acad. Sci. U.S.A.</u> 93:14082-14087 (November 1996)	

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			Application Number	10/518,472	
			Filing Date		
			First Named Inventor	Ito, Masashi	
			Art Unit	Not yet assigned	
			Examiner Name	Not yet assigned	
Sheet	4	of	6	Attorney Docket Number	082368-001500US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	BV	KIM, V. Narry <i>et al.</i> , "Minimal requirement for a lentivirus vector based on human immunodeficiency virus type 1," <i>Journal of Virology</i> 72(1):811-816 (January 1998)		
	BW	KREYMAN, B. <i>et al.</i> , "Glucagon-like peptide-1 7-36: A physiological incretin in man," <i>The Lancet</i> 2(8571):1300-1304 (December 5, 1987)		
	BX	LEE, Hyun Chul <i>et al.</i> , "Remission in models of type 1 diabetes by gene therapy using a single-chain insulin analogue," <i>Nature</i> 408:483-488 (November 23, 2000)		
	BY	LUND, Anders H. <i>et al.</i> , "Transcriptional silencing of retroviral vectors," <i>J. Biomed. Sci.</i> 3:365-378 (1996)		
	BZ	MARKO, Olga <i>et al.</i> , "Isolation of a preadipocyte cell line from rat bone marrow and differentiation to adipocytes," <i>Endocrinology</i> 136(10):4582-4588 (1995)		
	CA	MEIER, Juris J. <i>et al.</i> , "Glucagon-like peptide 1 as a regulator of food intake and body weight: therapeutic perspectives," <i>European Journal of Pharmacology</i> 440:269-279 (2002)		
	CB	MICK, Gail G. <i>et al.</i> , "White adipocyte vascular endothelial growth factor: regulation by insulin," <i>Endocrinology</i> 143(3):948-953 (2002)		
	CC	MIYAO, Yasuyoshi <i>et al.</i> , "A simplified general method for determination of recombinant retrovirus titers," <i>Cell Structure and Function</i> 20:177-183 (1995)		
	CD	MOJSOV, Svetlana <i>et al.</i> , "Insulinotropin: Glucagon-like peptide I (7-37) co-encoded in the glucagon gene is a potent stimulator of insulin release in the perfused rat pancreas," <i>J. Clin. Invest.</i> 79:616-619 (February 1987)		
	CE	MORGENSTERN, Jay P. and Harmut Land, "Advanced mammalian gene transfer: high titre retroviral vectors with multiple drug selection markers and a complementary helper-free packaging cell line," <i>Nucleic Acids Research</i> 18(12):3587-3596 (1990)		
	CF	MUZYCZKA, N., "Use of adeno-associated virus as a general transduction vector for mammalian cells," <i>Current Topics in Microbiology and Immunology</i> 158:97-129 (1992)		
	CG	NAGAMATSU, Shinya <i>et al.</i> , "Adenovirus-mediated preproinsulin gene transfer into adipose tissues ameliorates hyperglycemia in obese diabetic KKA <sup>y</sup> mice," <i>FEBS Letters</i> 509:106-110 (2001)		
	CH	NALDINI, Luigi <i>et al.</i> , "In vivo gene delivery and stable transduction of nondividing cells by a lentiviral vector," <i>Science</i> 272:263-267 (April 12, 1996)		
	CI	NIWA, Ohtsura <i>et al.</i> , "Independent mechanisms involved in suppression of the Moloney leukemia virus genome during differentiation of murine teratocarcinoma cells," <i>Cell</i> 32:1105-1113 (April 1983)		
	CJ	POESCHLA, Eric <i>et al.</i> , "Development of HIV vectors for anti-HIV gene therapy," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 93:11395-11399 (October 1996)		
	CK	POESCHLA, Eric M. <i>et al.</i> , "Efficient transduction of nondividing human cells by feline immunodeficiency virus lentiviral vectors," <i>Nature Medicine</i> 4(3):354-357 (March 1998)		
	CL	PRATS, Herve <i>et al.</i> , "High molecular mass forms of basic fibroblast growth factor are initiated by alternative CUG codons," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 86:1836-1840 (March 1989)		

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	CM	RAPER, S.E. and J.M. Wilson, "Cell transplantation in liver-directed gene therapy," <u>Cell Transplant</u> 2(5):381-400 (September-October 1993)	
	CN	ROSE, John K. and Carol J. Gallione, "Nucleotide sequences of the mRNA's encoding the vesicular stomatitis virus G and M proteins determined from cDNA clones containing the complete coding regions," <u>Journal of Virology</u> 39(2):519-528 (August 1981)	
	CO	RUSSELL, David W. and A. Dusty Miller, "Foamy virus vectors," <u>Journal of Virology</u> 70(1):217-222 (January 1996)	
	CP	SHINNICK, Thomas M. <i>et al.</i> , "Nucleotide sequence of Moloney murine leukaemia virus," <u>Nature</u> 293:543-548 (October 15, 1981)	
	CQ	SORGE, Joe <i>et al.</i> , "Amphotropic retrovirus vector system for human cell gene transfer," <u>Molecular and Cellular Biology</u> 4(9):1730-1737 (September 1984)	
	CR	SPIRITO, Flavia <i>et al.</i> , "Cutaneous gene transfer and therapy: the present and the future," <u>J. Gene Med.</u> 3:21-31 (2001)	
	CS	SRINIVASAKUMAR, Narasimhachar <i>et al.</i> , "The effect of viral regulatory protein expression on gene delivery by human immunodeficiency virus type 1 vectors produced in stable packaging cell lines," <u>Journal of Virology</u> 71(8):5841-5848 (August 1997)	
	CT	STOFFEL, Markus <i>et al.</i> , "Human glucagon-like peptide-1 receptor gene: Localization to chromosome band 6p21 by fluorescence in situ hybridization and linkage of a highly polymorphic simple tandem repeat DNA polymorphism to other markers on chromosome 6," <u>Diabetes</u> 42:1215-1218 (1993)	
	CU	SUGIHARA, Hajime <i>et al.</i> , "Primary cultures of unilocular fat cells: Characteristics of growth in vitro and changes in differentiation properties," <u>Differentiation</u> 31:42-49 (1986)	
	CV	SUGIHARA, Hajime <i>et al.</i> , "Proliferation of unilocular fat cells in the primary culture," <u>Journal of Lipid Research</u> 28:1038-1045 (1987)	
	CW	SUGIHARA <i>et al.</i> , "Proliferation and differentiation of fat cells," <u>Nippon Rinsho</u> 53(Suppl):115-120 (1995)	✓
	CX	TAFURO, S. <i>et al.</i> , "Rapid retrovirus titration using competitive polymerase chain reaction," <u>Gene Therapy</u> 3:679-684 (1996)	
	CY	TANI, K. <i>et al.</i> , "Gene therapy using hematopoietic cells (Translation)," <u>Saishin Igaku</u> 56(2):258-267 (2001)	✓
	CZ	THORENS, Bernard <i>et al.</i> , "Cloning and functional expression of the human islet GLP-1 receptor: Demonstration that exendin-4 is an agonist and exendin-(9-39) an antagonist of the receptor," <u>Diabetes</u> 42:1678-1682 (1993)	
	DA	THYAGARAJAN, Bhaskar <i>et al.</i> , "Site-specific genomic integration in mammalian cells mediated by phage $\phi$ C31 integrase," <u>Molecular and Cellular Biology</u> 21(12):3926-3934 (June 2001)	
	DB	TOYOOKA <i>et al.</i> , "Gene therapy: Its present status and future direction (Translation)," <u>Folia Pharmacol. Jpn.</u> 116:158-162 (2000)	✓
	DC	WU, Min and Ayalew Mergia, "Packaging cell lines for simian foamy virus type 1 vectors," <u>Journal of Virology</u> 73(5):4498-4501 (May 1999)	

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	DD	XIAO, Weidong <i>et al.</i> , "Adeno-associated virus as a vector for liver-directed gene therapy," <u>Journal of Virology</u> 72(12):10222-10226 (December 1998)		
	DE	XIAO, Xiao <i>et al.</i> , "Efficient long-term gene transfer into muscle tissue of immunocompetent mice by adeno-associated virus vector," <u>Journal of Virology</u> 70(11):8098-8108 (November 1996)		
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Examiner Signature		Date Considered	
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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.